510(k) Summary
for
Silver Wound Pad

APR 1 6 2009

1. SPONSOR

Milliken Chemical
920 Milliken Rd., M-333
Spartanburg, SC 29303
Contact Person: John D. Bruhnke, Ph.D.

Telephone:864-503-2844
Date Prepared: March 9, 2009

2. DEVICE NAME

Proprietary Name:	Silver Wound Pad
Common/Usual Name:	Wound Dressing
Classification Name:	Dressing

3. PREDICATE DEVICES

- Smith & Nephew Exu-Dry® Non-Permeable Pad (K864011)

4. DEVICE DESCRIPTION

The Silver Wound Pad is a sterile, single-use wound care dressing for use in moist wound management. The Silver Wound Pad is offered in several configurations including 24" x 36" and 36 " x 36" The dressings are comprised of 5 layers, each performing a specific function; an occlusive synthetic bottom layer (not in contact with patient), two absorbent layers, a layer of a knitted composite fabric (containing polyester on one side and nylon on the other side; coated with 15 ± 5% Antimicrobial AlphaSan® RC 2000 contained in a polyurethane binder) and a contact layer of apertured polyethylene film. These layers are then stitched or heat-sealed together along the edge.

5. INTENDED USE

The Silver Wound Pad is indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, lymphoedema, dermatological wounds, and Stage I-IV dermal ulcers (vascular, arterial, venous, pressure and diabetic).

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Technological characteristics of the Silver Wound Pad and the predicate product are substantially equivalent in that they are both dressings suitable for use on partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, lymphoedema, dermatological wounds, and Stage I-IV dermal ulcers (vascular, arterial, venous, pressure and diabetic). The Silver Wound Pad substantially equivalent in design, function and intended use to the Smith & Nephew Exu-Dry® Non-Permeable Pad (K864011). The only significant difference between the Silver Wound Pad and the predicate device is that Silver Wound Pad contains a silver-based preservative in a polyurethane coating for control of microorganisms.

7. PERFORMANCE TESTING

Biocompatibility testing was performed in accordance with the International Organization for Standardization recommendations. Results of the biocompatibility tests demonstrate that the device is suitable for its intended use. Antimicrobial testing was performed which showed that Silver Wound Pad provides efficacy against gram-positive and gram-negative bacteria. Milliken believes that the data included in this submission including the technical characteristics and physical properties demonstrate that Silver Burn Pad is substantially equivalent in design, function and intended use to Exu-Dry®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Milliken & Company
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

APR 16 2009

Re: K083659
Trade/Device Name: Silver Wound Pad
Regulation Name: Unclassified
Product Code: FRO
Dated: March 31, 2009
Received: April 1, 2009

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to

premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

F.A. Padhame on b.R

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083659

Device Name: Silver Wound Pad

Indications for Use:

The Silver Wound Pad is indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, lymphoedema, dermatological wounds, and Stage I-IV dermal ulcers (vascular, arterial, venous, pressure and diabetic).

Prescription Use _X___ AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083659